

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION OF:

WHITSON, Debi

Serial No.: 09/802,546

Filed: March 9, 2001

PROCESS OF INTERFACING A
PATIENT INDIRECTLY WITH THEIR
OWN ELECTRONIC MEDICAL
RECORDS

Group Art Unit No.: 3626

Docket No. 36357

Examiner: PORTER, Rachel L.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED DECLARATION OF DEBI WHITSON UNDER 37 C.F.R. § 1.132

1. I, Debi Whitson, am making this declaration in support of the above-referenced patent application (the "Application"). I am the sole inventor named in the Application and owner of one hundred percent interest in the Application.

2. From 1994 to 1997 I was employed by the Federal Reserve Bank as the Senior Software Engineer in charge of designing and creating multi-state systems to track bank inspections and supervision. I was also responsible for developing and maintaining databases. In this capacity, I was required to attend many training programs and become an expert in multiple areas of software and database development. I directed programming teams, designed database and software applications, trained computer programmers, and replaced numerous outdated Federal Reserve software and database systems with updated systems.

3. In 1997, I began working for Paradigm Solutions, an electronic medical record (EMR) consulting company, as an EMR system manager/implementer. When Paradigm Solutions was purchased by Mid-America Cardiology in 1998, I did similar work for Mid-America Cardiology in addition to maintaining a private EMR system consulting practice on the side. In my work for Mid-America Cardiology and in my private consulting practice I met with physicians to determine their EMR needs and implemented EMR systems designed to meet those needs; designed, developed, and implemented software components not available with conventional EMR systems; worked with clinic management personnel and physicians to design workflows tailored for new EMR systems; trained personnel (physicians, nurses, office staff, etc.) to use EMR systems; resolved problems relating to all technical aspects of EMR applications and databases; and created software applications to query EMR databases to identify clinical trends and issues as requested on an *ad hoc* basis. During this time, I participated in many national training sessions, conventions, and programs to keep current with the EMR industry standards and needs.

3. As an individual with extensive experience in the electronic medical record system industry, I have been asked to provide this declaration to attest to the state of the art prior to the filing date of the Application. This includes the teachings of U.S. Patent No. 6,151,581 to Kraftson et al., U.S. Patent No. 5,496,175 to Oyama et al., and U.S. Patent Application Publication No. 2005/0187794 to Kimak.

4. Independent claim 1 of the Application is directed towards a process of allowing a patient to have limited input access to their electronic medical record. The method comprises providing the patient with a machine readable card including a questionnaire concerning the patient's medical history, environment, symptoms, or other

pertinent information for answering by the patient, and interfacing the card with a scanning type machine to convert the patient's written answers to a data stream. The data stream is then arranged into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record, and the formatted data is sent to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health.

5. In 1999 I began developing a commercial product, now called PatientLink™, embodying the invention recited in claim 1 of the Application. By 2002 PatientLink™ had become so commercially successful that I left Mid-America Cardiology to run a business selling and supporting PatientLink™. To date, more than 900 PatientLink™ systems have been installed in medical clinics. I have not heavily advertised or promoted PatientLink™, and in fact, my only effort to promote PatientLink™ has been renting a booth at a trade show twice a year. The vast majority of my customers come from prior customer referrals or word-of-mouth.

6. To my knowledge no other product is commercially available that performs the functions recited in claim 1—namely scanning information from a machine readable card including patient medical history, environment, and symptoms, and arranging the information into a data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record. The ability to obtain patient information directly from the patient and automatically input the patient's information into an EMR has been a valuable tool for medical offices. Due to this, my sales of PatientLink have significantly increased ever year, with an even greater

increase in the past two years. In the first two full years of sale in 2001 and 2002, I sold approximately 50 systems. By the fifth year, I sold approximately 66 systems, and in the past two years, I have seen a significant increase due to word-of-mouth and customer referrals. In particular, I have sold an average of approximately 157 systems in each of 2006 and 2007. This amounts to an approximate 137% increase in sales in years 2006 and 2007.

7. Prior to my invention, it was not known in the art how to automatically read data from a machine-readable form including a patient's medical history, environment, and symptoms and convert the data to a data stream arranged into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's patient-specific electronic medical record. Such protocol structures were not designed to include a patient's medical history, environment, and symptoms.

8. Until I developed the application invention, I was not aware that such protocol structures could be used to export a patient's medical history, environment, and symptoms to the patient's electronic medical record. To my knowledge, at the time of the invention no one skilled in this art was aware that such protocol structures could be used export a patient's medical history, environment, and symptoms to the patient's electronic medical record.

9. Representatives from companies specializing in EMR systems have inquired about the functionality of PatientLink™. To my knowledge, none have successfully duplicated the functionality recited in claim 1.

10. Prior to my invention, Health Level Seven (HL7) laboratory records were used in the industry only for communicating traditional laboratory test results, such as chemistry,

From:HOVEY, WILLIAMS

913 647 9057

07/10/2008 15:08 #085 P.006/006

hematology, and radiology test results, between laboratory and hospital computer systems. Skilled artisans in this industry were not aware that HL7 laboratory records could be used to import information relating to a patient's medical history, environment, symptoms into the patient's electronic medical record.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,


Debi Whitson

7-10-08
Date